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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,416	05/09/2001	Chaitan Khosla	300622000501	5252

25225 7590 02/12/2004  
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EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1639

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/852,416

**Applicant(s)**

KHOSLA ET AL.

**Examiner**

Padmashri Ponnaluri

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 61-75 is/are pending in the application.
- 4a) Of the above claim(s) 61-67 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/03, 4/02.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's election without traverse of group XXI, claims 29-55, 58 (which are now canceled and replaced with new claims 61-75), in Paper No. 10172003 is acknowledged.
2. Newly submitted claims 61-67 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly added claims 61-67 are drawn to a macrolide or glycosylated macrolide (product-by-process), which has no specific core structure and read on any other macrolide compounds, for example the restricted groups XXIV or XXV compounds read on the compounds of claim 61. NOTE that the compounds of groups XXIV or XXV were restricted from original elected compound of group XXI (claim 29).

Since claim 61 (a macrolide or glycosylated macrolide) was not presented earlier and even if it were presented earlier would have restricted out from the Group XXI, and applicant has not traversed the restriction of groups XXIV or XXV, the invention of group XXI has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-67 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Response to Species Election Requirement***

3. Applicants in the response file don 10/17/03, in page 35 state that 'the claims have been amended to read on a single invention that closely approximates the subject matter of claim 29 and its dependent claims.' Thus it is considered that claim 29 compound of given formula read on the elected claims. Even though applicants have not elected the requested species election

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(see restriction requirement mailed on 4/17/03, page 9) for each group in claim 29 formula, from the response filed on 10/17/03 it is confirmed applicants wish to elect the following, and the elected compound in claim 68 has the following groups:

- a)  $R^1 - R^6$  are methyl groups (e.g., see applicants response page 36 filed on 10/17/03);
- b)  $X^2$  is =O (see claim 29);
- c)  $R^*$  is ethyl;
- d)  $X^3$  or  $X^4$  are considered as -OH or -H group (since claim 68 does not recite any glycosyl units represented by the groups).

4. Claim 75 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10172003.

#### *Status of Claims*

5. Claims 1-60 have been canceled and new claims 61-75 have been added by the amendment filed on 10/17/2003.

6. Claims 61-67 and 75 are withdrawn from consideration and Claims 68-74 are currently being examined in this application.

#### *Priority*

7. This application claims priority to several US Patent applications has been noted. However, applicants are requested to update the current status of the parent application data in the specification page 1.

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8. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The instant application is a continuation of 09/073,538 filed on 5/6/98; which is a CIP of application 08/846,247, filed on 4/30/97. The instantly claimed compound of claim 68 is broad and has not been disclosed in the 08/846,247 application. The compounds 11-13A, or 11-13B of figure 5A or 11-19A, 11-21A, 11-22A, CK7A, CK7B of figure 5B of application 08/846,247 are a species of genus claimed in the instant claim. The instant broad genus claim compound has no clear support in 08/846,247 application. Thus, the instantly claimed compound has effective filing date of 09/073,538 application filing date 5/6/98.

#### ***Information Disclosure Statement***

9. The information disclosure statements filed on 4/29/02 and 8/25/03 have been fully considered.

#### ***Specification***

10. The disclosure is objected to because of the following informalities: in the specification page 2, line 4, blank space regarding a reference is noted.

Appropriate correction is required.

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***Claim Objections***

11. Claims 68-74 are objected to because of the following informalities: the instant claim 68 is dependent on withdrawn claim 61. Applicants are requested to amend the claims. Appropriate correction is required.

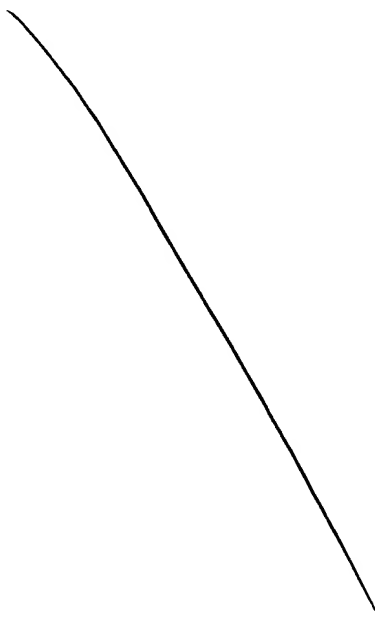
***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

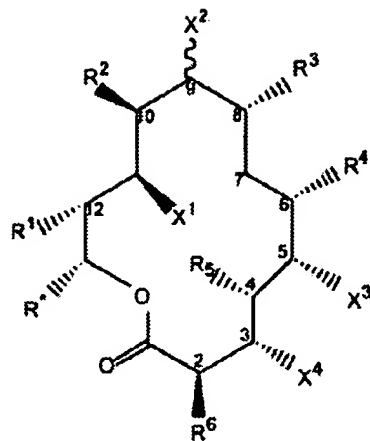
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 68-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claim recite a macrolide of formula :



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wherein R\* is methyl or ethyl;

each of R<sup>1</sup>-R<sup>6</sup> is methyl;

X<sup>1</sup> is OH or H; and/or

X<sup>2</sup> is =O, OH or H; and/or

X<sup>3</sup> is OH or H; and/or

X<sup>5</sup> is OH or H; and/or

a pi bond is present at positions 10-11, 8-9, 4-5 and/or 2-3; and wherein at least one of the following restrictions is present:

X<sup>1</sup> is H;

X<sup>2</sup> is OH or H;

X<sup>3</sup> is H;

X<sup>4</sup> is H; and/or

a pi bond is present at positions 10-11, 8-9, 4-5 and/or 2-3.

According to the instant claim, X<sup>3</sup> is either -OH or -H group; and X<sup>4</sup> -H group (only when pi bond is present). The instant claimed genus of compounds with X<sup>3</sup> is either -OH or -H group; and X<sup>4</sup> -H group, and X<sup>2</sup> -OH has no support in the originally filed application or claims.

The compound claimed in Claims 68-74 have no clear support in instant original specification or the claims, thus considered as new matter.

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If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. Claims 68-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 recites macrolide compound of formula, which is indefinite for the following reasons:

a) the claims recites  $X^1$  is OH or H and/or, it is not clear what does applicants mean by and/or which other groups represent  $X^1$ ;

b) the claims recites  $X^2$  is OH or H and/or, it is not clear what does applicants mean by and/or which other groups represent  $X^2$ ;

c) the claims recites  $X^3$  is OH or H and/or, it is not clear what does applicants mean by and/or which other groups represent  $X^3$ ;

d) the claims recites  $X^5$  is OH or H and/or, it is not clear what does applicants mean by and/or which other groups represent  $X^5$ ;

e) the claim does not define  $X^4$  if pi bond is not present.

Claims 69-74 recite process limitations of claim 61, which is currently not being examined in this application.



***Claim Rejections - 35 USC § 102***

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 68-74 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,060,234 (KATZ et al, filing date 5/16/97).

NOTE the instant claims get the effective filing date of 5/6/98.

The disclosed compounds of Katz reference claims clearly anticipate the instant claimed compounds.

3. Claims 68-74 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,033,883 (BARR et al) (filing date 12/11/97, effective filing date 12/18/96).

The applied reference has a common inventor (Gary W. Ashley) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

The deoxyerythronolide B (e.g., see figure 2) of the reference clearly anticipates the claimed compound.

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### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 68-74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,558,942 B1 (KHOSLA et al). Although the conflicting claims are not identical, they are not patentably distinct from each other because the broadly claimed compound reads on the reference compounds.

### ***Conclusion***

18. No claims are allowed.

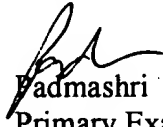
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884.

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The examiner is on Flex Schedule and can normally be reached from Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

  
Padmashri Ponnaluri  
Primary Examiner  
Art Unit 1639

Pp  
23 January 2004